REMARKS

Reconsideration of the rejections set forth in the Final Office Action mailed December 3, 2001 and entry of the present amendment is requested because Applicant respectfully submits that the Amendment places the application in a condition for allowance or in better form for consideration on appeal.

In response to the Final Office Action, claims 17, 32, and 41 have been canceled without prejudice, and claims 1, 16, 31, 33, and 44 have been amended.

In the Final Office Action, the Examiner rejected claims 1-3, 5-10, 15-17, 20-22, 31-36, 40, and 42-45 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,441,515 ("the Khosravi et al. '515 reference"), and claims 37-39 and 41 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Khosravi et al. '515 reference in view of U.S. Patent No. 6,042,605 ("the Martin et al. reference"). In addition, claims 1-3, 5, 6, 8-10, 31-36, 40, 42, 44, 45, 51-55, 57, and 58 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,895,406 ("the Gray et al. reference"), and claims 16, 29, and 30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Gray et al. reference in view of U.S. Patent No. 5,836,964 ("the Richter et al. reference").

Because none of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, as amended, reconsideration and withdrawal of the rejections is respectfully requested.

Turning first to the judicially created doctrine of double patenting rejection, Applicants submit herewith a Terminal Disclaimer, disclaiming the terminal part of any patent granted on the

present application that would extend beyond the expiration date of U.S. Patent No. 6,290,720. Therefore, the double patenting rejections should be withdrawn.

With respect to the § 102(b) rejections, differences between the present claims and the Khosravi et al. '515 reference have been explained previously in the Amendment filed on February 12, 2001. To summarize, the Khosravi et al. '515 reference discloses a stent that includes a flat sheet including a mesh pattern that is rolled into a spiral shape in both a reduced diameter form and an expanded diameter form. The Khosravi et al. '515 reference discloses that the stent may be expanded by a balloon catheter (plastically expanded) or by the expansive properties of the stent itself (self-expanding). (Col. 6, lines 39-44). In either case, the disclosed stent expands by unrolling, as may be seen, for example, in FIGS. 2 and 3 of the Khosravi et al. '515 reference. The Khosravi et al. '515 reference does not teach or suggest that the mesh pattern itself comprises an unstretched or peripherally contracted condition when the stent is in a contracted condition, and a stretched or peripherally expanded condition to facilitate expansion of the coiled-up sheet to one or more enlarged conditions, as presently claimed.

Turning to claim 1, the Khosravi et al. '515 reference does not teach or suggest a plurality of stretchable elements formed in a coiled-up sheet, the stretchable elements comprising an unstretched condition to facilitate placement in a delivery device in the contracted condition and a stretched condition to facilitate expansion of the coiled-up sheet to the one or more enlarged conditions upon deployment from the delivery device, the stretchable elements defining a width about the periphery that is smaller in the unstretched condition than in the stretched condition. Although the Khosravi et al. '515 reference discloses a coiled-sheet stent that includes honeycomb-like cells, there is no teaching or suggestion that these cells are provided in an unstretched condition when placed in a

delivery device and a stretched condition upon deployment from the delivery device. At most, the Khosravi et al. '515 reference discloses that these cells may allow increased flexibility. (Col. 5, lines 10-33).

As explained between page 8, line 10 and page 10, line 20 of the present application, a stent in accordance with the present invention has two properties that contribute to its expansion upon deployment. First, the coiled-sheet may at least partially unroll, and, second, the stretchable elements may expand to the stretched condition. Because the Khosravi et al. '515 reference only discloses that the stent may unroll during deployment, claim 1 and its dependent claims are neither anticipated nor otherwise obvious in light of the Khosravi et al. '515 reference.

For similar reasons, claims 16, 51, and 55, and their dependent claims, are also neither anticipated nor otherwise obvious in light of the Khosravi et al. '515 reference. In particular, claim 16 recites that the stretchable elements are plastically deformable towards an unstretched condition at a temperature at or below about 25 degrees Celsius, and biased to expand about the periphery from the unstretched condition towards a stretched condition when exposed to a temperature at or above body temperature. The Khosravi et al. '515 reference fails to teach or suggest such a temperature-activated shape memory, but instead discloses a coiled-sheet stent that may unroll either by plastically deforming the stent OR due to a bias provided by expansive properties of the stent material.

With respect to claim 31, the Khosravi et al. '515 reference does not teach or suggest forming a plurality of stretchable elements in a sheet, the stretchable elements being expandable along a width of the sheet between an unstretched condition and a stretched condition, the stretchable element being biased to expand towards the stretched condition when exposed to a temperature at or

above body temperature, and constraining the coiled-up sheet with the stretchable elements plastically deformed to the unstretched condition at a temperature at or below about 25 degrees Celsius. Similarly, the Khosravi et al. '515 reference fails to teach or suggest a method for delivering such a stent, as recited in claim 44.

Turning to the Richter et al. reference, a stent is disclosed that is formed from a sheet that is cut and rolled until the edges meet, whereupon the edges are joined together. (Col. 1, lines 32-36). FIG. 4 of the Richter et al. reference shows "a stent 31 formed by the process of steps 10-16," i.e., including step 16, which recites that "the edges 28 are joined together by any suitable process, such as spot welding." (Col. 3, lines 31-42). Thus, the Richter et al. reference merely discloses an enclosed tubular stent, and fails to teach or suggest a coiled-sheet stent that includes overlapping inner and outer longitudinal sections and is unrollable between a contracted condition and one or more enlarged conditions, as claimed. In addition, the Richter et al. reference does not disclose, teach, or suggest using a temperature-activated shape memory material. For these reasons, the present claims are neither anticipated nor otherwise obvious in light of the Richter et al. reference.

Finally, turning to the remaining references, neither the Martin et al. reference nor the Gray et al. reference discloses, teaches, or suggests anything about coiled-sheet stents, and, in particular, does not teach or suggest a coiled-sheet stent that both unrolls and has stretchable elements that may be expanded to facilitate expansion of the coiled-sheet stent, as claimed.

At most, the Gray et al. reference discloses an enclosed tubular stent that includes longitudinal bands (6) that are connected by circumferential links (7). (Col. 4, lines 15-20). Although the Gray et al. reference discloses that the stent may be formed from a shape memory alloy such that the stent expands automatically (Col. 5, lines 8-19), there is no teaching or suggestion of a

temperature-activated shape memory that includes the stent being plastically deformed at a lower temperature, and becoming biased to expand at a higher temperature. Accordingly, the present claims are also neither anticipated nor otherwise obvious in light of the Gray et al. reference.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,

LYON & LYON LLP

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By _____
William A. English
Reg. No. 42,515
Attorneys for Applicants

633 West Fifth Street
Suite 4700
Los Angeles, CA 90071-2066
(949) 567-2300

VERSION WITH MARKINGS SHOWING CLAIM AMENDMENTS:

1. (amended) A stretchable stent, comprising:

a coiled-up sheet having overlapping inner and outer longitudinal sections extending generally parallel to a longitudinal axis thereof, and defining a periphery, the coiled-up sheet being unrollable between a contracted condition and one or more enlarged conditions; and

a plurality of stretchable elements formed in the coiled-up sheet, the stretchable elements *comprising*~~being expandable about the periphery between~~ an unstretched condition to facilitate placement in a delivery device in the contracted condition and a stretched condition to facilitate expansion of the coiled-up sheet to the one or more enlarged conditions upon deployment from the delivery device, *the stretchable elements defining a width about the periphery that is smaller in the unstretched condition than in the stretched condition.*

16. (amended) A stretchable stent, comprising:

a coiled-up sheet having overlapping inner and outer longitudinal sections extending generally parallel to a longitudinal axis thereof, the coiled-up sheet being expandable between a contracted condition and one or more enlarged conditions, the coiled-up sheet defining a periphery in a plane substantially perpendicular to a longitudinal axis thereof;

a plurality of locking elements extending from the inner longitudinal section for engaging openings in the outer longitudinal section to selectively secure the coiled-up sheet in the one or more enlarged conditions; and

a plurality of stretchable elements formed in the coiled-up sheet, the stretchable elements having a shape memory *such that the stretchable elements are plastically deformable towards an*

unstretched condition at a temperature at or below about 25 degrees Celsius, and biased to expand about the periphery from *the* ~~an~~ unstretched condition towards a stretched condition when exposed to a ~~predetermined~~ temperature *at or above body temperature.*

31. (amended) A method for making a coiled-sheet stent, the method comprising the steps of:

providing a substantially flat sheet defining a length and a width, *the sheet comprising a shape memory material*;

forming a plurality of stretchable elements in the sheet, the stretchable elements being expandable along the width of the sheet between an unstretched condition and a stretched condition, *the stretchable elements being biased to expand towards the stretched condition when exposed to a temperature at or above body temperature*;

rolling the flat sheet about the width into a coiled-up sheet having overlapping inner and outer longitudinal sections;

constraining the coiled-up sheet with the stretchable elements *plastically deformed to* ~~in~~ the unstretched condition *at a temperature at or below about 25 degrees Celsius.*

33. (amended) The method of claim *31* ~~32~~, wherein the step of forming the stretchable elements comprises the steps of:

forming the stretchable elements in the sheet in the stretched shape; and

heat treating the sheet to program the stretched shape into the shape memory material.

44. (amended) A method for deploying a coiled-sheet stent at a target treatment location within a patient's body, the method comprising the steps of:

providing a coiled-sheet stent comprising a temperature-activated shape memory material, the coiled-sheet stent comprising a plurality of stretchable elements having a shape memory defining an unstretched condition and a stretched condition, the stretchable elements being biased to assume the stretched condition when exposed to a temperature at or above body temperature;

providing the coiled-sheet stent in a contracted condition within a distal end of a tubular sheath at a temperature substantially below body temperature with the stretchable elements *plastically deformed to* ~~in~~ the unstretched condition;

percutaneously introducing the distal end of the sheath into a blood vessel of a patient;

advancing the distal end of the sheath to a target treatment location, the coiled-sheet stent becoming exposed to a temperature within the patient of at least about body temperature during advancement, whereby the stretchable elements become biased to assume the stretched shape; and

deploying the coiled-sheet stent at the target treatment location, the coiled-sheet stent *unrolling and* at least partially expanding towards an enlarged condition due to the bias of the stretchable elements towards the stretched shape.